



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0112]

Guidance for Industry on Chemistry, Manufacturing, and Controls Information--Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #216 entitled "Chemistry, Manufacturing, and Controls (CMC)

Information--Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use."

The purpose of this document is to provide recommendations on what documentation to submit to support the CMC information for fermentation-derived intermediates, drug substances, and related drug products for veterinary medicinal use.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 14, 2011 (76 FR 13629), FDA published the notice of availability for a draft guidance entitled "Chemistry, Manufacturing, and Controls (CMC) Information--Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use" giving interested persons until May 30, 2011, to comment on the draft guidance. FDA received one comment on the draft guidance. No substantive changes were made in finalizing this guidance document.

The guidance announced in this notice finalizes the draft guidance dated March 14, 2012.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance will represent the Agency's current thinking on this

topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance have been approved under OMB control number 0910-0032.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: March 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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